

Nephros SSU-H - Instructions for Use

INTRODUCTION

Information on this sheet must be read before the use of this device to ensure safe and effective operation.

Sterility: The device is sterilized by ethylene oxide.

Recommended Storage: Between 5 and 35°C (41 and 95°F).

INDICATIONS

Description: The Nephros SSU-H is a disposable in-line water ultrafilter used to filter EPA quality drinking water. The filter retains bacteria, viruses and endotoxin. By providing ultrapure water for washing and drinking, the filters aid in infection control. The filter produces water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands.

Single Use: The device is intended for single use. Once installed the filter is intended to be used for up to 3 months. After such time the unit should be replaced and discarded. Do not attempt to sanitize or re-sterilize it.

CONTRAINDICATIONS

Medical: The filter is not intended to provide water that can be used as a substitute for USP sterile water.

Chemical: The SSU-H retains biological contaminants. To obtain chemically pure water it is necessary to use the filter in conjunction with other devices such as DI beds or RO systems.

WARNINGS & PRECAUTIONS

Pressure & Temperature: The SSU-H is designed for a maximum incoming water pressure of 75 psi (5 bar) and a maximum incoming temperature of 60°C (140°F).

Cyclic Use: The SSU-H is intended for a maximum of 5,000 on/off cycles in in-line use and 500 cycles in open discharge use.

Replacement: The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended that one establish a maintenance schedule of replacing the filter at least every 3 months dependent on water quality.

Water Monitoring: After installation of the SSU-H, periodic monitoring of the water is recommended.

INSTALLATION & REMOVAL

Note: If it is the first time a SSU-H is installed in a location, please refer to one of the *SSU-H Installation Guides*. Prior to handling a new filter it is recommended that one wash their hands and wear disposable gloves.

- Open a new filter blister pack and remove the port caps.
- Mark the label with the installation date.
- If installing the threaded version of the filter, turn off the water supply valve. For the quick connect version it is not necessary to turn off the water valves before disconnecting the filter as the female quick connectors have internal shut off valves.
- Disconnect the inlet of the used filter followed by the outlet.
- Seal the used filter ports with the caps to minimize water leakage.
- Remove the used filter from its mounting clamp and discard appropriately.
- Place the new filter in the clamp making sure the flow direction arrow points towards the water outlet.
- Connect the outlet line to the filter followed by the inlet line.

Note: Prolonged exposure of the filter to alkyl dimethyl benzyl ammonium chloride (ADBAC) may result in cracks to the external housing. It is recommended not to use ADBAC based cleaners.

OPERATION

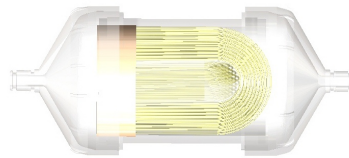
After a new SSU-H is installed, water should be run through the filter for approximately 30 seconds to purge it of trapped air. The pressure drop across the SSU-H generally reduces the flow rate by about ¼ to ½ of the rate without a filter. The filter should operate

for up to 3 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

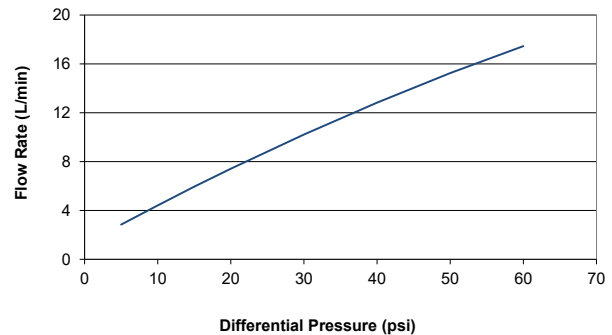
INTEGRITY TESTING

One can test the integrity of the filter using the following technique

- Disconnect the inlet port connection.
- Disconnect the outlet connection and connect a sterile 60 cc syringe to the outlet port using an adapter.
- With the inlet to drain, pump air into the filter using the 60 cc syringe until water stops flowing out the inlet port (2-3 syringe volumes).
- Attempt to push one final syringe volume of air into the filter. Hold the plunger down for 5 seconds then release it.
- If the plunger rises the filter integrity is assured. If it fails to rise it is recommended to replace the filter.



SSU-H - Clean Water Flow



Specifications	Nephros SSU-H
Sterilization Method	Ethylene Oxide
Max Inlet Pressure	75 psi (5 bar)
Max Inlet Temperature	60°C (140°F)
<u>Max # On/Off Cycles</u>	
In-Line Use	5,000
Open Discharge	500
<u>Filter Membrane</u>	Medisulfone®
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10 ¹¹ (B. diminuta)
Virus Retention	> 10 ⁸ (PhiX-174)
Endotoxin Retention	> 10 ⁵ EU/ml
Expected Life	up to 3 months

Medisulfone® is a registered trademark of Medica S.p.A.

Assembled at:

Medica S.p.A.
Medolla, Italy

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